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Adulteration of Ayurvedic Sexual Wellness Products with Phosphodiesterase 5 (PDE5) Inhibitors: A Threat to Standardization and Patient Safety

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Abstract

Concerns about side effects, safety, and the natural origin of Ayurvedic preparations marketed for sexual enhancement contribute to a rising global demand for these formulations. Research, however, has brought to light startling cases of adulteration of these products with the synthetic Phosphodiesterase-5 (PDE5) inhibitors sildenafil (Commonly known as Viagra), tadalafil, avanafil and vardenafil. The adulteration of a product with these compounds is a fundamental challenge to standardization, regulatory framework, and safety of the patient. This review describes the occurrences of adulteration, health challenges, regulatory frameworks, and the need for appropriate analytical techniques to determine the authenticity of these formulations and the trust of the patients in Ayurvedic sexual wellness preparations. The foremost issues in standardization of herbal medicines, in particular, the public health threat resulting from the undisclosed addition of sildenafil and other PDEs to Ayurvedic medicines are of special concern. The document unsupported inclusion of these ingredients in herbal products poses a significant threat to public health, and the recent surge in cross-border trade of Ayurveda and herbal medicines necessitates the enforcement of fundamental quality control and regulations. The adulteration on synthetic drugs, variability of herbal raw materials, and absence of appropriate analytical methodologies result in the unreliable description of Ayurvedic herbal medicines. The undocumented presence of sildenafil in herbal aphrodisiacs is alarming, as it poses serious health risks to the consumers and trust in herbal medicines. The major issues with standardization arise from variability in herbal materials, lack of consistent quality control, and clandestine adulteration with synthetic PDE5 inhibitors, all of which compromise efficacy and safety.

Keywords: Ayurvedic sexual wellness products; PDE5 inhibitors; Herbal medicine adulteration; Standardization and patient safety

Introduction

Ayurvedic sexual wellness products are commonly used for the management of conditions such as erectile dysfunction, premature ejaculation, and for promoting overall vitality [1,2]. Unlike synthetic medications, these formulations are traditionally perceived as natural and holistic. However, growing commercial pressure to provide rapid and tangible outcomes has led some manufacturers to surreptitiously add synthetic PDE5 inhibitors like sildenafil, tadalafil, avanafil and vardenafil to their products [3,4]. While these agents demonstrate proven efficacy, they are also associated with risks such as cardiovascular complications, adverse drug interactions, and contraindications in individuals with underlying comorbidities [5,6]. Undisclosed adulteration not only compromises consumer safety but also threatens the credibility of Ayurveda and its therapeutic integrity [7].

Prevalence of adulteration

Numerous international studies have identified the presence of PDE5 inhibitors in herbal products advertised as “natural” aphrodisiacs [3,4]. Advanced analytical techniques

such As High-Performance Liquid Chromatography (HPLC), Liquid Chromatography-Mass Spectrometry (LC-MS/MS), and Gas Chromatography-Mass Spectrometry (GC-MS) are frequently employed, consistently uncovering undeclared compounds like sildenafil and tadalafil in these formulations [4,6]. Both the World Health Organization (WHO) and regulatory authorities, including the US FDA and Central Drugs Standard Control Organization (CDSCO) of India, have issued public warnings regarding the adulteration of such products [8-10]. This practice is especially problematic because the concentrations of PDE5 inhibitors in these herbal preparations are highly variable, and in some cases, exceed established therapeutic limits. Such inconsistencies elevate the risk of overdose and significantly hinder objective clinical assessment of authentic Ayurvedic formulations.

Patient safety concerns

Exposed PDE5 inhibitors can be detrimental in the following ways:

Cardiovascular: Hypotension and arrhythmias and in some severe cases can even result in a myocardial infarction in people taking nitrates and/or antihypertensives [3,4].

Drug interactions: Potentially fatal complications with protease inhibitors (in patients with HIV), some antifungals, and certain classes of antibiotics [2,5].

Misuse and dependency: Self-consumption of PDE5 inhibitors and other "herbal supplements" under the assumption of having no side effects and therefore relying on them, often resulting in extreme overdoses [4].

Delayed medical attention: Slowing the pace at which a diagnosis is made and treatment is provided for potent medical ailments like diabetes and cardiovascular conditions due to the dependence on adulterated products [3,5].

Key regulatory and standardization measures [8-10]

Robust analytical testing: Adoption of advanced screening technologies such as LC-MS/MS and HPLC is essential for detecting adulterants, ensuring identity, purity, and strength as outlined in official pharmacopoeia standards.

Good Manufacturing Practices (GMP): Manufacturers must comply with GMP guidelines as mandated by the Drugs & Cosmetics Act and Rules (India), with periodic audits and monitoring to prevent contamination and intentional adulteration.

Transparency and labeling: Regulatory bodies require labels to disclose all active constituents, helping safeguard consumers and support authentic product claims.

Global harmonization: Organizations such as WHO, AYUSH, and the International Regulatory Cooperation for Herbal Medicines (IRCH) are working towards harmonized frameworks that improve international monitoring and align safety standards across countries.

Issues with standardization

Standardization of Ayurvedic sexual wellness products faces multiple challenges due to the complex nature of herbal formulations and the presence of adulterants. Firstly, the inconsistent composition of raw herbal materials- influenced by factors like plant species, geographical origin, harvesting season, and processing methods- leads to variability in active constituents [1,2]. Secondly, intentional adulteration with PDE5 inhibitors undermines the authenticity of the product and introduces unknown pharmacological effects, making it difficult to establish reliable dosage standards [3,4]. Thirdly, the lack of universally accepted quality control protocols for herbal products hinders consistent assessment across different manufacturers and laboratories [2,5]. Even when analytical techniques such as HPLC or LC-MS/MS are used, the wide range of herbal matrices complicates detection and quantification of both natural phytochemicals and synthetic adulterants [3,6]. Finally, insufficient regulatory enforcement and variability in labeling standards contribute to discrepancies between the claimed and actual content of these products [5,7]. These standardization challenges not only compromise product efficacy but also pose serious risks to patient safety, highlighting the urgent need for stringent quality control measures, harmonized guidelines, and advanced analytical methods.

Conclusion

The adulteration of Ayurvedic sexual wellness products with PDE5 inhibitors represents a dual threat: undermining the integrity of traditional medicine and endangering patient safety. Regulatory vigilance, advanced analytical methods, and strict enforcement of quality standards are essential to safeguard consumer trust and ensure the authenticity of Ayurvedic therapeutics. The urgent need is to balance consumer demand with ethical manufacturing practices to uphold Ayurveda's reputation as a safe and holistic system of medicine.

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